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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/530,165

08/22/2005

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753-48 PCT/US

5604

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09/03/2009

EXAMINER

AUDET, MAURY A

ART UNIT

PAPER NUMBER

1654

MAIL DATE

DELIVERY MODE

09/03/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                       |  |
|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/530,165 | <b>Applicant(s)</b><br>ZIEGLER ET AL. |  |
|                              | <b>Examiner</b><br>MAURY AUDET       | <b>Art Unit</b><br>1654               |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-7 and 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's amendment and response are acknowledged.

#### ***Election/Restrictions***

As stated previously, Applicant's election without traverse of Group I, claims 1-7 and 13-16, as drawn to the general formula I, bearing a single amino acid Lysine at AA2 (as the compound of the invention) in the reply filed on 12/3/07 is acknowledged. The claims have been examined only in so far as it reads upon the elected invention. Claims 8-12 and 17-19 are withdrawn from consideration as being drawn to non-elected subject matter.

#### ***Claim Rejections - 35 USC § 112 1<sup>st</sup> Written Description-Maintained***

The rejection of claims 1-2, 5-7, and 15 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, is maintained for the reasons of record. Applicant request for reconsideration based on the amendment of the claims to indicate the L-configuration on the stereocenter lysine is not found persuasive, because the claims are still claiming a "racemated or enantiomeric pure isomer", which can be construed to be ANOTHER racemate or enantiomer form. Thus the rejection is maintained.

The rejection is repeated below for continuity of the record:

*Vas-Cath Inc. V. Mahurka*, 19 USPQ2d 1111, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought; he or she was in possession of the invention. The invention, for purposes of the "written description" inquiry, is *whatever is now claimed*" (see page 1117).

A new review of the language of the claim indicates that these claims are drawn to a genus, i.e., *any racemate or enantiomer of the peptide of Formula I.*

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. *Regents of the University of California v. Eli Lilly & Co.*, 119 F3d 1559, 1569, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In *Regents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of nucleic acids by only their functional activity does not provide an adequate written description of the genus. The court indicated that, while applicants are not required to disclose every species encompassed by a genus, the description of the genus is achieved by the recitation of a representative number of species falling within the scope of the claimed genus. At section B(1), the court states "An adequate written description of a DNA ... requires a precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention".

There are no racemate or enantiomeric species structures that have been disclosed in the description such a peptide of Formula I would afford extension to these unknown compound

structures, and a genus comprising the same. There is substantial variability among racemates and enantiomers which do not permit the mere statement aforementioned as a substitute for the description of these specific structures.

One of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of which comprises any racemate or enantiomer of the peptide of Formula I. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is Claimed" (see *Vas-Cath* at page 1116).

#### ***Claim Observations***

As noted previously, in line with the international search report (citing only 2 "A" references) and the written opinion findings of the International Authority in related PCT/CH/2002/000670:

"In light of the documents cited in the international search report, it is considered that the invention as defined in the claims meets the criteria mentioned in Article 33(1) PCT, i.e. it appears to be novel and to involve an inventive step. "

The closest prior art of record uncovered by this Office in the structure hereof on the elected single amino acid lysine compound, other than only Applicant and this application, is simply noted for the teaching of the chemical name and CN of the compound, which Applicant can look up on STN if desired. The reference is merely noted, but not relied upon on (and hence the reference is not cited on an 892 or deemed necessary to forward to Applicant) was the dipeptide compound of (CN: 205439-22-1):

"Glycine, N6-[(1,1-dimethylethoxy)carbonyl]-N2-[(phenylmethoxy)carbonyl]-L-lysyl-2-[[2-[(aminoiminomethyl)amino]ethyl]thio]-, (2S)-"

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(cited in Hong et al. "Development of substrate for carboxypeptidase-B by employing thiaarginine peptides", Bulletin of the Korean Chemical Society (1998), 19(2), 189-193).

However, as Applicant has not claimed a dipeptide, but rather a single peptide, it was not entirely clear why this compound was returned, other than containing therein, the elected lysine compound as part of the internal structure. The latter was not found alone.

### ***Conclusion***

Applicant's submission of information (that the substituted glycine does not represent a naturally occurring amino acid?) submitted on page 6 of the response of 5/21/09 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MAURY AUDET whose telephone number is (571)272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MAA, 8/31/09

/Maury Audet/  
Examiner, Art Unit 1654  
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